MAR - 5 2010

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitter: Medical Numerics, Inc
20410 Observation Drive, Suite 210
Germantown, MD 20876

Contact Person: Douglas M. Tucker, PhD, MBA
Business Development

Telephone: (240) 686-3460 extension 405

FAX: (240) 686-3464

Preparation Date: December 10, 2009

Device Trade Name(s): Integrated Stimulus Delivery System (ISDS) Optimum
Integrated Stimulus Delivery System (ISDS) Premium

Common Name: functional MR Imaging (fMRI) Stimulus Delivery Hardware System

Device Classification: Magnetic resonance diagnostic device (21 CFR 892.1000)
Class II
Product Code LNH

Equivalent Device Identification:

K080515	FMRI HARDWARE SYSTEM
K052571	MINDSTATE FUNCTIONAL DATA ACQUISITION DEVICE

Device Description: For a patient undergoing a functional MR imaging examination, the ISDS hardware components present visual and auditory stimuli to a patient and collect responses from that patient while the patient is in the bore of the MR scanner. Hardware components interface the ISDS computer system to the MR scanner in order to synchronize operation of the ISDS with the MR imaging procedure. The stimuli delivery (type of stimuli, stimuli presentation order, timing of stimuli presentation, etc.) is controlled by a proprietary software application.

COMPUTER SUB-SYSTEM

This Computer Sub-System provides general purpose computing capabilities for the ISDS. The computer system provides an environment for execution of the application software and provides physical infrastructure for interfacing with other components of the architecture (MR Interface, Stimulus Delivery Hardware) and external systems (MR host system and users).

PATIENT INTERFACE SUB-SYSTEM

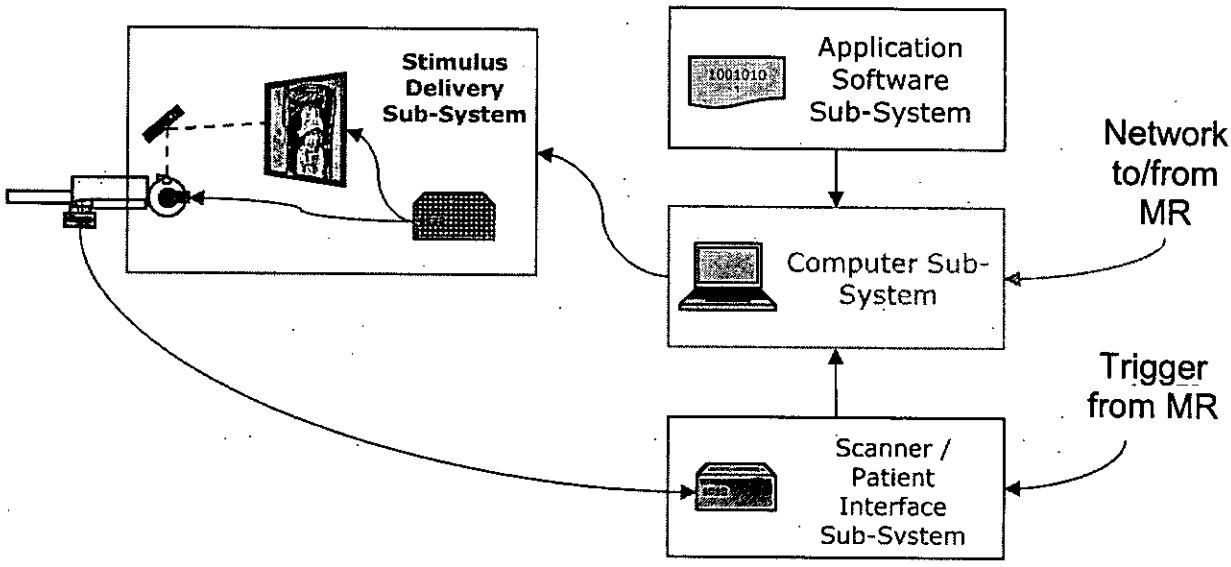
The MR Scanner and Patient Response Interface Sub-System communicate patient responses and MR image acquisition events to the host computer. The MR Scanner interface enables the ISDS computer sub-system to synchronize operation with the MR scanner. The Patient Response Interface Sub-System collects responses from that patient while the patient is in the bore of the MR scanner.

STIMULUS DELIVERY SUB-SYSTEM

The Stimulus Delivery Sub-System communicates audio and video stimuli to the patient during the MR examination while the patient is in the bore of the MR Scanner.

APPLICATION SOFTWARE SUB-SYSTEM

The Application Software Sub-System provides the ISDS application functionality. Primary functionality includes the ability to develop new and modify existing fMRI paradigms, and to execute specific paradigms during an fMRI examination.



Intended Use:

The Integrated Stimulus Delivery System (ISDS), both Optimum and Premium models, is indicated for use by trained medical professionals to aid in the performance of functional Magnetic Resonance Imaging (fMRI) examinations based on Blood Oxygen Level Dependent (BOLD) contrast. The ISDS works with GE 1.5T and 3.0T Magnetic Resonance (MR) scanners with BrainWave™ software installed. The ISDS presents to the patient specific visual and audio stimuli with predetermined order and timing patterns and collects keypad responses; all ISDS functions are synchronized with the ongoing patient MR imaging examination.

Statement of Substantial Equivalence: The Integrated Stimulus Delivery System (ISDS) is substantially equivalent to the named predicate devices. All of the devices have similar intended uses and use the same or similar technology.

Summary of Testing: The ISDS has been tested and found to be safe and effective at meeting its requirements and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR - 5 2010

Medical Numerics, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K093336
Trade/Device Name: Integrated Stimulus Delivery System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 19, 2010
Received: February 22, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

[redacted]

K093336

Indications for Use

510(k) Number (if known):

Device Name: Integrated Stimulus Delivery System

Indications For Use:

The Integrated Stimulus Delivery System (ISDS), both Optimum and Premium models, is indicated for use by trained medical professionals to aid in the performance of functional Magnetic Resonance Imaging (fMRI) examinations based on Blood Oxygen Level Dependent (BOLD) contrast. The ISDS works with GE 1.5T and 3.0T Magnetic Resonance (MR) scanners with BrainWave™ software installed. The ISDS presents to the patient specific visual and audio stimuli with predetermined order and timing patterns and collects keypad responses; all ISDS functions are synchronized with the ongoing patient MR imaging examination.

Prescription Use ___XX___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093336